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CLEARINGHOUSE RULE 98-142

Comments

[NOTE: All citations to “Manual” in the comments below are to the Administrative Rules Procedures Manual, prepared by the Revisor of Statutes Bureau and the Legislative Council Staff, dated September 1998.]

1. Statutory Authority

a. The rule does not comply with the statutory requirement set forth at s. 93.12, Stats., to designate the laboratory examinations the department deems necessary for the protection of the health of the public. The rule repeals the provisions in s. HSS 165.03 that designate the water, milk and food examinations which are necessary for the protection of the health of the public. If the department is intending that the lists of tests in s. ATCP 77.02 (1) will serve this purpose, this should be clarified.

b. The rule fails to comply with the following statutory requirement, set forth at s. 93.12 (3), Stats., as follows:

Substantial failure of any laboratory to show evidence of quality control procedures, sufficient to comply with current standards and practice as prescribed by the department, shall result in denial or revocation of the certificate of approval.

In order to comply with the statute, the rule must be revised to set forth standards and practices for quality control procedures and to provide for the denial or revocation of a certificate of approval for failure of a laboratory to follow those standards and practices.

c. The rule fails to comply with the following statutory requirement, set forth at s. 93.12 (4), Stats.:

A certificate of approval shall be revoked by the department if the minimum standards established by the department for certification are not met within two successive evaluations.

Sections ATCP 77.24 (1) and 77.34 (1) should be revised to comply with the statutory requirement.

2. Form, Style and Placement in Administrative Code

a. The chapter, section and paragraph titles in the rule should be rewritten to conform to proper drafting style. [See s. 1.05 (2) (a), (b) and (d), Manual.]

b. Currently, s. HSS 165.03 has only one subsection. As amended, that subsection will have only one paragraph. It is not appropriate drafting style to divide a rule unit into only one subunit. [See s. 1.03 (intro.), Manual.] Therefore, each of the subdivisions in current par. (a) should become subsections. As redrafted, s. HSS 165.03 should read as follows:

HSS 165.03 Examinations necessary for the protection of the health of the public. The department designates the following examinations of body fluids, tissues, discharges, respiratory and environmental air as necessary for the health of the public:

(1) Microbiology tests.

...

c. In s. ATCP 77.01 (1), “, as defined under sub. (15), at a laboratory” is unnecessary.

d. The definition provided for the term “operator” in s. ATCP 77.01 (11) should be rewritten to read: “(11) “Operator” means a person who owns or controls a laboratory or that person’s employees or agents.” However, including the employees and agents within the definition of “operator” is unworkable in several parts of the rule. For example, s. ATCP 77.04 (1) (intro.) requires an operator to apply for certification of a laboratory. Paragraph (a) requires the application to include the operator’s correct legal name and address. Clearly, this requirement applies only to the owner or person in control of a laboratory and not to an operator’s employees.

e. It appears that s. ATCP 77.02 (1) (intro.) should be rewritten as follows:

(1) WHO MUST BE CERTIFIED. Except as provided under sub. (4), no individual may perform any of the following tests to determine whether milk, water or food complies with public health standards required under federal or state law unless the laboratory at which the test is performed has been certified under s. ATCP 77.08 for the performance of that test:

f. Section ATCP 77.04 (1) (e) 3. should be rewritten to clarify that in order to obtain certification, a laboratory must meet the proficiency evaluation requirements set forth in s. ATCP 77.24 (1) or ATCP 77.34 (1).

g. Should s. ATPC 77.06 (1) specify that an annual certification fee must be paid for each separate laboratory at which a test is to be performed?

h. In s. ATPC 77.06 (4) (a), the phrase “at the operator’s laboratory” should be changed to “the laboratory for which the operator is seeking certification.”

i. Section ATPC 77.08 (1) states that the department “may” certify an operator if the operator and laboratory comply with the requirements of the chapter. Should “may” be changed to “shall”? If not, the rule should specify the circumstances under which certification may be denied to an operator who has met the requirements of the chapter.

j. Section ATPC 77.08 (1) authorizes the department to conditionally certify an operator pending action by the operator to correct deficiencies. Is there a maximum length of time for which an operator may be conditionally certified? Are there certain deficiencies for which a conditional certificate may not be issued?

k. It appears that under ch. ATPC 77, the “laboratory administrator” will be fulfilling the role previously fulfilled by the laboratory director, as set forth under s. HSS 165.20. However, s. ATPC 77.12, relating to laboratory administrators, does not set forth any qualifications that must be met by a laboratory administrator. In contrast, s. HSS 165.20 (2), which is repealed by the rule, sets forth various educational and experience requirements for directors of milk, food and water laboratories.

l. In s. ATPC 77.14 (1) (c), it appears that the second occurrence of “operator” should be changed to “department.”

m. Section ATPC 77.14 (2) (a) authorizes the department to inspect a certified laboratory whenever the operator “materially alters laboratory facilities, equipment or *procedures*” (emphasis added). Should the rule establish a requirement that the operator notify the department of any material alteration of laboratory procedures? It does not appear that the notice requirement in s. ATPC 77.10 (3) is sufficient to ensure that notice is provided in this instance.

n. In s. ATPC 77.14 (2) (intro.), it appears that “authority” should be changed to “laboratory.”

o. In the third line of s. ATPC 77.22 (2) (a), it appears that “under” should be inserted after “tests.”

p. Section ATPC 77.22 (3) should be rewritten to clearly specify the standards that must be met for an analyst to obtain certification to perform a test. In addition, the rule should clearly state that an analyst may not perform a test unless the analyst is certified to perform that test. Also, should s. ATPC 77.22 (4) (b) specify that a test may not be performed at a operator’s laboratory if, as a result of a staffing change, there is no longer at least one analyst certified to perform the test working at the operator’s laboratory?

q. In s. ATPC 77.24 (2), it appears that the terms “operator” and “analyst” are used interchangeably.

r. In s. ATCP 77.24 (3), it is unclear what the requirements are for approval of a proficiency evaluator. Is approval by the Food and Drug Administration a prerequisite to departmental approval? If so, this requirement should be set forth in the text of the rule.

s. In s. ATCP 77.32, what action should be taken if an analyst is found not to be proficient?

t. Section ATCP 77.34 (5) (a) should specify how often an operator must examine “at least 10 samples.” Is this an annual requirement?

5. Clarity, Grammar, Punctuation and Use of Plain Language

a. In the last sentence under the heading “Laboratory Facilities” in the analysis to the rule, it appears that “it” should be changed to “laboratory.”

b. Each of the subdivisions in s. ATCP 77.02 (1) (c) should end with a period.

c. In s. ATCP 77.04 (1) (intro.), “initial” should be inserted before “certification.”

d. In s. ATCP 77.14 (2) (b), it is unclear what is meant by “a new analyst.” Is this term meant to refer to an analyst who has not previously performed a certain test or to an analyst who has been newly hired to work at the laboratory?

e. In s. ATCP 77.20 (2) (a), the first occurrence of “and” should be changed to “or.”

f. Section ATCP 77.22 (3) should clearly state that an analyst may not perform any test under s. ATCP 77.02 (1) (a) or (b) unless the analyst has been certified by the department to perform that test.

g. Although the analysis to the rule states that “[t]his rule does not make major changes in the current lab certification program,” the reduction in the number of proficiency evaluations that must be performed by a certified laboratory appears to be major. For example, s. HSS 165.14 (2) (a) 11., which is repealed by the rule, requires a laboratory which engages in milk testing to evaluate, at a minimum, 34 proficiency testing specimens each year, while the proposed rule, in s. ATCP 77.24 (1), would require the evaluation of only one specimen annually.

h. Section ATCP 77.32 should state whether an analyst must be certified in order to perform tests under s. ATCP 77.02 (1) (c), as is required for analysts who perform tests under s. ATCP 77.02 (1) (a) and (b). In addition, must a laboratory have at least one analyst certified to perform a test under s. ATCP 77.02 (1) (c) as a precondition to the department certifying the operator to perform that test?